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Signed: Minna Cotter

Minna Cotter

In the United States Patent and Trademark Office

Applicant: NANTEL, et al.
Applicant's Ref: 0053.00
Application No: 09/731,317
Filed: December 6, 2000
Title: SYSTEM AND METHOD FOR NON-DESTRUCTIVE MASS SENSING

Examiner: PHAM, Hoa Q.
Group Art Unit: 2877

January 14, 2005
San Carlos, California

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Final Rejection of January 14, 2004 and Advisory Action of July 6, 2004, the Applicant of the above-referenced patent application (hereinafter Appellant) appeals to the Board of Patent Appeals and Interferences. Appellant hereby requests the reversal of the Final Rejection.

(1) *Real Party in Interest*

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 150 Industrial Road; San Carlos, California 94707.

(2) *Related Appeals and Interferences*

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) *Status of Claims*

Claims 1-50, 52-57, 59-64, 66-69, and 71-73 are presently pending in the case. Claims 51, 58, 65, and 70 have been cancelled. Claims 1-50, 52-57, 59-64, 66-69, and 71-73 have been finally rejected by the Examiner. The rejections of each of these claims are hereby appealed.

(4) *Status of Amendments*

An amendment After Final was filed on June 14, 2004. In an Advisory Action mailed on July 14, 2004, the Examiner indicated that the amendments would be entered for the purposes of appeal. Thus, it is believed that the amendment of June 14, 2004 is due entry.

(5) *Summary of the Invention*

The present invention is directed to the measurement of the mass of a powder pharmaceutical agent. Pharmaceutical agents are often prescribed in terms of unit dosages. It is important for these unit dosages to consistently contain a desired amount of the pharmaceutical agent in order to assure that a patient will be receiving a safe and effective amount of the pharmaceutical agent. When the pharmaceutical agent is in the form of a fine powder, such as a powder composed of particles having a mass median diameter from about 0.1 μm to about 100 μm, the consistent filling of the desired amount of the pharmaceutical powder into a unit dosage can be difficult. Because of the cohesiveness and compressibility of pharmaceutical powders, simple volume measurements are not always accurate measures of the mass of the agent in a unit dosage form. Accordingly, it is often necessary to destructively remove the powder from random unit dosage samples so that confidence can be gained as to the consistency of powder that is

being filled into the unit dosage forms. This process suffers from being random and from being destructive in that the randomly selected samples must be discarded.

Appellant has invented a method and apparatus that allows powder pharmaceutical agents to be more consistently and reliably filled into a unit dosage form with improved processing throughput. As shown in Figure 12 and described in the specification beginning on page 12 line 15, by applying energy to the pharmaceutical powder (step 90), measuring a response resulting from the application of energy (step 92), and determining the mass of the powder substance based on the measured response (step 94), the mass of a unit dose of the pharmaceutical powder can be determined in a non-destructive manner. A process of this type has heretofore not been used in the pharmaceutical industry and is particularly useful for pharmaceutical powders that are difficult to handle, such as those that have a mass median diameter from about 0.1 μm to about 100 μm. A particular version of a system for carrying out the invention is described in connection with Figure 3. In this version a light source (20) is used to apply energy and a detector (22) is used to measure the response resulting from the application of energy.

(6) ***Grounds of Rejection to be Reviewed on Appeal***

Appellant requests review of the Examiner's following grounds of rejection:

(i) Claims 1-7, 12, 14-19, 30-33, 50, 52, 57, 59, 64, and 66 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,147,618 to Richardson et al (hereinafter Richardson et al); and

(ii) Claims 8-11, 13, 20-29, 34-38, 40-49, 53-56, 60-63, 67-69, and 71-73 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al in view of GB patent publication 2077422 to Pryor et al (he0072einafter Pryor et al), U.S. Patent 4,461,363 to Loy (hereinafter Loy), U.S. Patent 3,744,582 to Withnell et al (hereinafter Withnell et al), U.S. Patent 4,640,376 to Hinzpeter (hereinafter Hinzpeter), and U.S. Patent 4,825,454 to Annis et al (hereinafter Annis et al).

(7) *Argument*

Appellant believes each of claims 1-50, 52-57, 59-64, 66-69, and 71-73 to be improperly rejected and to therefore be allowable for the following reasons.

The Examiner improperly rejected independent claim 1 under 35 USC 103(a) as being unpatentable over Richardson et al. Claim 1 is to a method for measuring the mass of a powder substance, the method comprising, inter alia, applying energy to a powder substance which comprises a pharmaceutical agent, wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm. Richardson et al does not disclose or suggest a method of measuring the mass of a pharmaceutical powder. Furthermore, one of ordinary skill in the art at the time Appellant's invention was made would not have found it obvious, based on the teachings of Richardson et al, to arrive at Appellant's claimed invention because (1) there is no motivation to modify the teachings of Richardson et al, (2) when considering the teachings of Richardson et al as a whole one of ordinary skill in the art would not find it obvious to derive Appellant's invention, absent the use of impermissible hindsight reasoning, and (3) Richardson et al constitutes non-analagous art and one of ordinary skill in the art would not have considered the teachings of Richardson et al.

Richardson et al is directed to the measurement of the mass of a propellant in an ammunition cartridge. Richardson et al states in column 1, lines 41-48:

> Although there is some concern about overfilling a cartridge casing, the primary concern is with underfilling them, since a cartridge lacking a sufficient powder might supply a weak explosion within a muzzle of a gun, so that the bullet head would not be propelled from the muzzle. If this occurred, there would then be a danger that the weapon would explode when the next cartridge was fired.

Richardson et al deals with an improvement in the manufacture of ammunition. Richardson et al's improvement overcomes a problem associated with measuring the mass of "products such as ammunition cartridges where the mass of the contents is relatively small compared to the mass of the entire product" (Column 1 line 66 though column 2 line 1). Nowhere within Richardson et al is there a discussion of the measurement of the mass of a pharmaceutical agent, and there is certainly no discussion of the measurement of the mass of a pharmaceutical powder having a mass median diameter from about 0.1 μm to about 100 μm.

There is no motivation for one of ordinary skill in the art at the time of Appellant's invention to modify Richardson et al to arrive at Appellent's invention as set forth in claim 1. There is simply no suggestion within Richardson et al that the disclosure of Richardson et al would be applicable or advantageous for measuring the mass of a pharmaceutical powder. The Examiner attempts to make up for this lack of suggestion and motivation by stating that the "rationale for this modification would have risen from the fact that depending on what product to be measured to be measured the system will be modified so that an accuracy of the measurement if obtained (sic)" (Final Office action, page 3 lines 1-3). Appellant respectfully disagrees that this statement constitutes sufficient motivation for rendering claim 1 unpatentable. According to the Examiner's reasoning, a person of ordinary skill in the art would read Richardson et al, would be motivated to improve accuracy and would then arrive at Appellent's invention. The Examiner does not provide any reasoning as to why the person of ordinary skill in the art would modify the teachings of Richardson et al for pharmaceutical purposes. Furthermore, the Examiner does not provide any evidence that improved accuracy is needed in the filling of pharmaceutical powders. The Examiner's rejection is deficient in this regard. Since no motivation exists in the applied reference and since no motivation has been otherwise provided, it is improper to posit that a person of ordinary skill in the art would have found it obvious to modify Richardson et al in a way that would render Appellant's claim 1 unpatentable.

The Examiner has used impermissible hindsight reasoning to improperly reach the conclusion that one of ordinary skill in the art would have found it obvious at the time the invention was made to modify Richardson et al to arrive at the invention set forth in Appellant's claim 1. The Examiner's conclusion is without evidentiary basis. Instead, the Examiner has proposed a modification to Richardson et al that one of ordinary skill in the art would not have found obvious without having been privy to the Appellant's teachings. If one of ordinary skill in the art were to have read Richardson et al and considered the teachings of Richardson et al as a whole, they would not have found it obvious to modify Richardson et al so that it is useful for measuring the mass of pharmaceutical powders. As discussed above, Richardson et al discusses that the disclosed system is useful when measuring contents where the mass of the contents is relatively small compared to the mass of the entire product (e.g. powder propellant within an ammunition cartridge). Pharmaceutical powders do not fall within this category. The mass of a pharmaceutical receptacle, such as a plastic capsule casing and a thin metal or plastic foil, is not relatively large compared to the mass of the entire pharmaceutical product (and in some cases, such as pharmaceutical tablets, there is no receptacle at all). Therefore, one of ordinary skill,

after having considered the teachings of Richardson et al as a whole, would not have been found it desirable to modify Richardson et al to be used with pharmaceutical powders because the problem solved by Richardson et al was not a problem confronted by the pharmaceutical industry. Therefore, only with improper hindsight reasoning would one reach a conclusion that Appellant's claim 1 is unpatentable over Richardson et al.

Richardson et al is non-analogous prior art. Richardson et al is primarily concerned with ammunition cartridges. One of ordinary skill in the art of pharmaceutical processing would not look to the ammunition art for overcoming problems encountered in processing pharmaceuticals. Powder propellants are not similar to pharmaceutical powders. Richardson et al deals with an industry that is the polar opposite of the pharmaceutical industry. This is further evidenced by the fact that Richardson et al published more than twenty years prior to the Appellant's present filing. During that time, the pharmaceutical industry failed to modify the teachings of Richardson et al for measuring the mass of pharmaceutical powders. Furthermore, the Examiner has failed to show the existence of a problem in the pharmaceutical industry that one of ordinary skill in the art would have looked to solve. Thus, Richardson et al constitutes non-analogous art. Accordingly, the teachings of Richardson et al should be disregarded.

Therefore, as set forth above, there is no motivation to modify the teachings of Richardson et al; when considering the teachings of Richardson et al as a whole one of ordinary skill in the art would not find it obvious to derive Appellant's invention, absent the use of impermissible hindsight reasoning; and Richardson et al constitutes non-analagous art. Any one of these would render the Examiner's rejection of claim 1 improper. Thus, Appellant requests that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of claim 1.

Independent claim 14 is also not rendered unpatentable by Richardson et al. Claim 14 is to a method comprising, inter alia, filling a metering chamber defining a certain volume with a powder substance which comprises a pharmaceutical formulation, wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm. Richardson et al does not disclose a powder substance as claimed as discussed above and does not render the claim unpatentable. In addition, claim 14 recites the step of "filling a metering chamber defining a certain volume with a powder substance which comprises a pharmaceutical agent". Richardson et al does not disclose or suggest the filling of a metering

chamber and the measurement of mass within the metering chamber. Instead, Richardson et al measures the mass within an ammunition cartridge. Accordingly, claim 14 is not rendered unpatentable by Richardson et al for this additional reason. Appellant requests reversal of the rejection thereof.

Additionally, independent claim 17 is not rendered unpatentable by Richardson et al. Claim 17 recites "directing a beam of light onto a powder substance which comprises a pharmaceutical agent, wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm." Richardson et al does not disclose a powder pharmaceutical as claimed, as discussed above. Furthermore, Richardson et al does not disclose directing a beam of light onto a powder substance which comprises a pharmaceutical formulation and wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm. Accordingly, the rejection of claim 17 as being unpatentable over Richardson et al should be reversed.

Richardson et al does not render claim 21 unpatentable, either. Claim 21 includes the step of "filling the chamber with a powder substance which comprises a pharmaceutical formulation, wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm". This step is not disclosed or suggested by Richardson et al. Thus, Richardson et al does not render the claim unpatentable and the rejection is requested to be reversed.

Independent claims 30 and 39 are also not rendered unpatentable by Richardson. Claim 30 is to a system comprising, inter alia, a metering chamber that is adapted to receive a powder substance and a cavity for receiving the powder substance when it is ejected from the metering chamber. Richardson et al does not disclose a system as claimed. In the Richardson et al system, propellant for ammunition is filled directly into a cartridge. Richardson et al does not disclose a metering chamber, as claimed. Furthermore, if the cartridge of Richardson et al is considered to be a metering chamber, then Richardson et al does not disclose a cavity, as claimed. Like claim 30, claim 39 recites the combination of a metering chamber and a cavity. Since Richardson et al does not disclose all features claimed, it does not render claim 30 or claim 39 unpatentable.

Claims 2-13, 50, 52-57 depend from claim 1; claims 15, 16, and 59-63 depend from claim 14; claims 18-20, 64, and 66-68 depend from claim 17; claims 22-29, 69, and 71 depend from claim 21; claims 31-38 and 72 depend from claim 30; and claims 40-49 and 73 depend from claim 39. Since each of these claims includes all of the limitations of the claim from which it depends, these claims are also not rendered unpatentable by Richardson et al. In addition, these dependent claims recite other features that further distinguish the claims.

The Examiner also improperly rejected claims 8-11, 13, 20-29, 34-38, 40-49, 53-56, 60-63, and 67-73 under 35 USC 103(a) as being unpatentable over Richardson et al in view of Pryor et al, Loy, Withnell et al, Hinzpeter, and Annis et al. These references do not make up for the deficiencies discussed above and do not serve to render any of the independent claims unpatentable. Accordingly, Appellant requests reversal of the rejections.

(8) ***Appendix***

A copy of the claims involved in the appeal is attached hereto.

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

NEKTAR THERAPEUTICS
(formerly INHALE THERAPEUTIC SYSTEMS)

Dated: 08 JUN 2006

By: _____
Guy V. Tucker
Reg. No. 45,302

Please send all correspondence to:
Guy Tucker
Nektar Therapeutics
(formerly Inhale Therapeutic Systems, Inc.)
150 Industrial Road
San Carlos, CA 94070
Phone: (650) 620-5501
Fax: (650) 620-6395

APPENDIX

1. A method for measuring the mass of a powder substance, the method comprising:

applying energy to a powder substance which comprises a pharmaceutical agent, wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm;

measuring a response resulting from the application of energy; and

determining the mass of the powder substance based on the measured response.

2. A method as in claim 1, further comprising volumetrically metering the powder substance prior to applying the energy.

3. A method as in claim 2, wherein the metering step comprises depositing the powder substance within a metering chamber.

4. A method as in claim 1, wherein the energy applying step comprises directing electromagnetic radiation onto the powder substance.

5. A method as in claim 1, wherein the energy applying step comprises directing light onto the powder substance.

6. A method as in claim 5, wherein the measuring step comprises measuring light transmitted through the powder substance, and wherein the determining step comprises correlating the measured light with an associated mass.

7. A method as in claim 5, wherein the measuring step comprises measuring light emitted from the powder substance, and wherein the determining step comprises correlating the measured light with an associated mass.

8. A method as in claim 5, wherein the measuring step comprises measuring an interference pattern caused by transmitted or emitted light from the powder substance

interfering with the light directed onto the powder substance, and wherein the determining step comprises correlating the interference pattern with an associated mass.

9. A method as in claim 1, wherein the energy applying step comprises applying current or voltage to the powder substance, wherein the measuring step comprises measuring the impedance of the powder substance, and wherein the determining step comprises correlating the impedance with an associated mass.

10. A method as in claim 1, wherein the energy applying step comprises applying vibrational energy to the powder substance, and wherein the measuring step comprises measuring the energy dissipation caused by the powder substance.

11. A method as in claim 10, wherein the step of applying vibrational energy comprises vibrating a piezoelectric element to subject the powder substance to pressure changes, wherein the measuring step comprises measuring the vibrational frequency of the piezoelectric element after energy has been dissipated by the powder substance, and wherein the determining step comprises comparing the measured vibrational frequency with a natural oscillating frequency of the piezoelectric element, and correlating the change in frequency with an associated mass.

12. A method as in claim 1, further comprising comparing the determined mass with a range of masses that defines an acceptable unit mass range to determine whether the measured powder substance is within the acceptable range.

13. A method as in claim 1, further comprising processing the response using tomography.

14. A method for determining whether a metered volume of a powder substance contains a unit mass, the method comprising:

filling a metering chamber defining a certain volume with a powder substance which comprises a pharmaceutical agent, wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm;

applying energy to the powder substance while within the metering chamber;

measuring a response resulting from the application of energy; and

determining the mass of the powder substance based at least in part on the measured response.

15. A method as in claim 14, further comprising comparing the determined mass with a range of masses that defines an acceptable unit mass range to determine whether the determined mass falls within the acceptable range.

16. A method as in claim 14, further comprising ejecting the powder substance from the metering chamber, and applying the energy and measuring the response while the ejected powder is traveling away from the metering chamber.

17. A method for measuring the mass of a powder substance, the method comprising:

directing a beam of radiation onto a powder substance which comprises a pharmaceutical agent, wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm;

measuring the transmittance or emittance of radiation from the powder substance, or an interference pattern caused by transmitted or emitted radiation from the powder substance interfering with the beam; and

determining the mass of the powder substance based at least in part on the measured transmittance or emittance of radiation, or the interference pattern.

18. A method as in claim 17, further comprising depositing the powder substance within a metering chamber and passing the beam through the metering chamber.

19. A method as in claim 18, wherein the depositing step comprising drawing the powder into the metering chamber with a vacuum.

20. A method as in claim 17, further comprising comparing the determined mass with a range of masses that defines an acceptable unit mass range to determine whether the measured powder substance is within the acceptable range.

21. A method for determining whether a unit mass of a powder substance has been metered, the method comprising:

passing a calibrating beam of radiation at a certain intensity through a metering chamber that defines a certain volume;

measuring the intensity of the calibrating beam after passing through the chamber;

filling the chamber with a powder substance which comprises a pharmaceutical formulation, wherein the powder substance comprises particles having a mass median diameter from about 0.1 μm to about 100 μm;

passing a measuring beam of radiation at the certain intensity through the powder substance;

measuring the intensity of the measuring beam after passing through the powder substance;

determining the transmittance of the measuring beam through the powder substance; and

determining the mass of the powder substance based at least in part on the transmittance of the measuring beam.

22. A method as in claim 21, wherein the transmittance is determined by subtracting the measured intensity of the measuring beam from the measured intensity of the calibrating beam.

23. A method as in claim 21, wherein the filling step further comprises drawing a vacuum within the metering chamber to assist in capturing falling powder into the chamber.

24. A method as in claim 23, wherein the metering chamber includes a filter upon which the powder substance rests, and further comprising passing the calibrating beam and the measuring beam through the filter.

25. A method as in claim 23, wherein the metering chamber is included within a rotatable drum, and further comprising rotating the drum between multiple positions where the intensity of the calibrating beam is measured, where the powder substance is deposited in the chamber, and where the intensity of the measuring beam is measured.

26. A method as in claim 25, further comprising rotating the drum to another position and ejecting the powder substance from the chamber and into a receptacle.

27. A method as in claim 26, further comprising repeating the step of rotating the drum between the multiple positions to deposit another mass of powder substance into another receptacle.

28. A method as in claim 21, further comprising comparing the determined mass with a range of masses that defines an acceptable unit mass range to determine whether the measured powder substance is within the acceptable range.

29. A method as in claim 28, further comprising varying the amount of vacuum and/or the rate at which the powder substance is permitted to fall in a subsequent filling of the metering chamber based on the value of the measured mass in comparison to the acceptable range of masses.

30. A system for measuring the mass of a powder substance, the system comprising:

a metering chamber that defines a certain volume and that is adapted to receive a powder substance;

an energy source disposed to supply energy to the powder substance;

at least one sensor to measure a response from the powder substance due to the application of energy from the energy source;

a processor coupled to the sensor to determine a mass of the powder substance held within the metering chamber based at least in part on the measured response; and

a cavity for receiving the powder substance when it is ejected from the metering chamber.

31. A system as in claim 30, wherein the energy source comprises a source of electromagnetic radiation disposed to direct electromagnetic radiation onto the powder substance.

32. A system as in claim 31, wherein the sensor is selected from a group of sensors consisting of a radiometer and a reflectometer.

33. A system as in claim 31, wherein the processor is configured to determine the mass of the powder substance by correlating transmitted or emitted light measured by the sensor with an associated mass.

34. A system as in claim 31, wherein the processor is configured to determine the mass of the powder substance by correlating a measured interference pattern measured by the sensor with an associated mass.

35. A system as in claim 30, wherein the energy source comprises an electrode that is adapted to pass electrical current through the powder substance, wherein the sensor comprises a sensing electrode and circuitry to measure the capacitance of the powder substance.

36. A system as in claim 30, wherein the energy source comprises a vibratable element that is adapted to apply vibrational energy to the powder substance, and wherein the sensor is configured to measure an amount of energy dissipation caused by the powder substance.

37. A system as in claim 36, wherein the vibratable element comprises a piezoelectric element that is adapted to supply pressurize air pulses to the powder substance, wherein the sensor further comprises circuitry to determine the vibrational frequency of the piezoelectric element after energy has been dissipated by the powder substance, and wherein the processor is configured to compare the measured vibrational frequency with a natural oscillating frequency of the piezoelectric element, and to correlate the change in frequency with an associated mass.

38. A system as in claim 36, wherein the processor is further configured to compare the determined mass with a range of masses that defines an acceptable unit mass range to determine whether the measured powder substance is within the acceptable range.

39. A system for measuring the mass of a powder substance, the system comprising:

a metering chamber that defines a certain volume and that is adapted to receive a powder substance;

a radiation source disposed to pass a beam of radiation through the metering chamber;

at least one sensor to detect radiation transmitted or emitted from the powder substance;

a processor coupled to the sensor to determine a mass of the powder substance held within the metering chamber based at least in part on the detected radiation; and

a cavity for receiving the powder substance when it is ejected from the metering chamber.

40. A system as in claim 39, wherein the processor is further configured to determine the mass of the powder substance by associating the loss of transmitted light, an interference pattern, or the stimulation of fluorescence with a stored mass value.

41. A system as in claim 40, wherein the processor is configured to determine the loss of transmitted light by comparing an intensity value of the beam after passing through the powder substance with an intensity value of a beam from the radiation source passing through the chamber in the absence of the powder substance.

42. A system as in claim 39, wherein the metering chamber includes a filter at a bottom end upon which the powder substance is adapted to rest, and wherein the radiation source is disposed to pass a beam through the filter and then through the chamber.

43. A system as in claim 42, further comprising a vacuum source in communication with the chamber to assist in drawing the powder substance into the chamber.

44. A system as in claim 43, further comprising a rotatable drum in which the chamber is disposed, and wherein the radiation source is included within the drum.

45. A system as in claim 44, further comprising a powder fluidization apparatus disposed above the drum that is adapted to supply fluidized powder to the chamber.

46. A system as in claim 45, further comprising a pair of sensors, and wherein the processor is configured to rotate the chamber past one of the sensors when the chamber is empty of powder, to rotate the chamber into alignment with the powder fluidization device to

permit the chamber to be filled with powder, and to rotate the chamber past the other sensor when the chamber is filled with powder.

47. A system as in claim 46, further comprising code used by the processor to compare the determined mass of the powder with a range of acceptable mass values, and wherein the processor is configured to alter the amount of vacuum and/or operation of the fluidization apparatus depending on the outcome of the comparison.

48. A system as in claim 39, further comprising code used by the processor that includes a relationship between the amount of transmitted light, an interference pattern, or the amount of fluorescence and the associated mass of the powder substance when the powder substance fills the chamber.

49. A system as in claim 39, wherein the radiation source comprises a laser and wherein the sensor comprises a lens and a radiometer.

50. A method as in claim 1, wherein the powder substance further comprises a pharmaceutically acceptable excipient.

51. (Cancelled)

52. A method as in claim 1, wherein the powder substance comprises individual particles having a mean size that is in the range from about 1 μm to about 5 μm.

53. A method as in claim 3, wherein a vacuum is applied to the metering chamber during the depositing of the powder substance within the metering chamber.

54. A method as in claim 3, wherein the powder substance is deposited within the metering chamber from a hopper positioned above the metering chamber.

55. A method as in claim 54, wherein a vibratable element is provided within the hopper to assist in depositing the powder substance within the metering chamber.

56. A method as in claim 3, wherein the metering chamber is in a rotatable drum.

57. A method as in claim 14, wherein the powder substance further comprises a pharmaceutically acceptable excipient.

58. (Cancelled)

59. A method as in claim 14, wherein the powder substance comprises individual particles having a mean size that is in the range from about 1 μm to about 5 μm.

60. A method as in claim 14, wherein a vacuum is applied to the metering chamber when filling the metering chamber with the powder substance.

61. A method as in claim 14, wherein the powder substance is filled into the metering chamber from a hopper positioned above the metering chamber.

62. A method as in claim 61, wherein a vibratable element is provided within the hopper to assist in filling the powder substance into the metering chamber.

63. A method as in claim 14, wherein the metering chamber is in a rotatable drum.

64. A method as in claim 17, wherein the powder substance further comprises a pharmaceutically acceptable excipient.

65. (Cancelled)

66. A method as in claim 17, wherein the powder substance comprises individual particles having a mean size that is in the range from about 1 μm to about 5 μm.

67. A method as in claim 18, wherein the powder substance is deposited within the metering chamber from a hopper positioned above the metering chamber and wherein

a vibratable element is provided within the hopper to assist in depositing the powder substance within the metering chamber.

68. A method as in claim 18, wherein the metering chamber is in a rotatable drum.

69. A method as in claim 21, wherein the powder substance further comprises a pharmaceutically acceptable excipient.

70. (Cancelled)

71. A method as in claim 21, wherein the powder substance comprises individual particles having a mean size that is in the range from about 1 μm to about 5 μm.

72. A system as in claim 30, wherein the cavity is a cavity within a blister pack.

73. A system as in claim 39, wherein the cavity is a cavity within a blister pack.